REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Status of Claims:

Claims 7, 12, and 25 are amended and claims 6, 8, 28-67 and 70-86 are cancelled without prejudice or disclaimer. Claims 98-101 are added as new claims. Hence, claims 1-5, 7, 9-27, 68-69, and 87-101 are presented for examination.

Claim Objections:

Claims 7 and 25 are objected to as being dependent on cancelled claim 6. Each of claims 7 and 25 is amended to be dependent on claim 1. Claim 12 is also amended herein to correct a dependency relationship addressed in a previous objection, as described in Applicant's remarks presented in response to that previous objection.

Claim Rejections:

Claims 1, 9-16, 68, 87, 88, 89, 91, 92, 93, 95 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al (U.S. Patent No. 4,994,047) in view of Bobo, Sr. (U.S. Patent No. 5,573,007).

Claims 2 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Bobo, Sr., and further in view of Ash et al (U.S. Patent No. 6,042,561).

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Bobo, Sr., and further in view of Ash et al, and yet further in view of Brange et al (U.S. Patent No. 4,472,385).

Claims 3 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Bobo, Sr., and further in view of Brange et al.

Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Bobo, Sr., and further in view of Brange, and yet further in view of Nelson (U.S. Patent No. 5,702,372).

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Bobo, Sr., and further in view of Ekwuribe et al (U.S. Patent No. 6,309,633).

Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatenable over Walker in view of Bobo, Sr., and further in view of Van Antwerp et al. (U.S. Patent No. 6,443,942).

Each of the above rejections is respectfully traversed, in view of the following remarks. In particular, none of the references of record, alone or in combination, teach or suggest the claimed invention.

Claim 1 recites a stabilizing catheter for protein drug delivery to a user comprising a tubing including at least one layer, wherein the at least one layer includes one or more materials that reduce diffusion of small molecules through the tubing, and wherein the one or more materials of the at least one layer includes materials selected from at least polytetrafluoroethane, saran (PVOC), polysulfone, hydrophilic glass, derivatives of these materials, and mixtures of these materials.

The Examiner acknowledges that claims 1 and 10 differ from Walker. In particular, the Examiner stated that claims 1 and 10 differ from Walker in calling for the layer to comprise saran. However, the Examiner stated that Bobo teaches (at column 8, lines 11-19) a catheter comprising a layer of saran that serves to minimize gas or liquid permeability and prevent migration of matter through the tubing. The Examiner further stated that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Walker to include a layer of saran as taught by Bobo to minimize gas or liquid permeability and prevent migration of matter through the tubing.

The characterization of the Bobo patent and combination of Bobo with Walker in the manner proposed in the Office Action is respectfully traversed. In particular, the cited portion of the Bobo patent (column 8, lines 11-19), describes a "flaccid membrane which forms a wall or

portion of the membrane-walled chamber 30,48." The material (including Saran) that Bobo describes for the membrane is selected to be flaccid, pliable and have minimal gas or liquid permeability. Bobo teaches to hold a gas under pressure by the membrane material and to allow the membrane material to flex inward or outward. In this regard, Bobo discloses a material with minimal gas permeability (to hold the gas within the chamber 30,48) and with suitable flexibility to move inward and outward, depending upon the pressure applied to the membrane.

In particular, Bobo describes a gas-column pressure monitoring catheter that includes a gas-filled, membrane-walled chamber 30, 48 that is formed on the outer surface of the catheter 12. (Bobo, Sr., Col. 7, ll. 40-43.) The chamber 30, 48 has a flaccid membrane 24, 40 that moves or translate inwardly to compress the gas within the chamber, when pressure is exerted against the outer surface of the membrane, and to move or translate outwardly to lower the gas pressure, when pressure against the outer surface of the membrane is decreased. (Bobo, Sr., Col. 7, l. 60 to Col. 8, l. 2). The membrane 24, 40 is attached to the outside of specific portions of the catheter body 20, but does not form the catheter body, itself. Instead, for each embodiment, Bobo teaches to employ a different structure and material for membrane 24, 40 than is used for the catheter body 20 as shown in Figs. 4a, 4b, 6b, and 7a of the Bobo, Sr. patent. In Fig. 2a, Bobo shows the membranes as being flexed or bowed outward from the catheter body 20.

Thus, Bobo teaches to employ flexible material with minimal gas or liquid permeability, for a flexible membrane portion of a catheter. However, Bobo does not teach or suggest using that flexible membrane material as the catheter body material. Rather, it would seem that such a material would not provide a sufficient rigidity to function as a catheter body. It is also noted that Bobo does not teach or suggest to line or coat the catheter body with Saran (but only provides the Saran material to cover a gas chamber formed in the catheter body). Furthermore, Bobo's limited use of such material as a flexible membrane to cover a gas chamber of a gas-pressure monitor structure on a catheter would not teach or suggest forming the catheter body (or providing a layer or coating on the catheter body) with Saran.

In contrast, the cannula structure described by Walker et al. does not include a flexible membrane (or any form of a gas pressure translating portion) and does not include a gas pressure monitoring structure. Thus, one skilled in the art would not employ the flexible membrane

described by Bobo, Sr. on a cannula structure described by Walker et al. Because the cannula structure described by Walker et al. has no flexible membrane, one skilled in the art would not have found it obvious to employ the flexible membrane material described by Bobo, Sr. on the cannula described by Walker et al.

While the Examiner stated that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Walker to include a layer of saran as taught by Bobo to minimize gas or liquid permeability and prevent migration of matter through the tubing, the above comments explain that Bobo does not teach or suggest employing a Saran material as a layer or coating on a cannula structure of Walker et al., because Walker et al.'s cannula structure has no gas chamber, no gas pressure monitoring structure and, thus, no need for a flexible membrane. As discussed above, Bobo's limited teaching of the use of Saran for a flexible membrane (with gas impermeability for the purpose of holding gas within the gas chamber) would not have let one or ordinary skill in the art to line or coat a cannula structure (having no gas pressure monitoring structure) as described by Walker with Saran. Accordingly, the rejections (which are each based, wholly or partially, on the Examiner's combination of Walker et al. and Bobo, Sr.) are respectfully traversed.

Furthermore, the requirements of the hydrophilic material in Walker suggests away from a combination with Bobo, Sr. Walker teaches a catheter with a hydrophilic layer that swells and softens upon contact with an aqueous liquid by absorbing the liquid. (Walker, col. 3, lines 4-7, and col. 4, lines 6-9). For the hydrophilic material in the hydrophilic layer, Walker specifies that the preferable softening ratio to be at least 2:1 after hydration. (Walker, col. 4, lines 42-45). As examples, Walker teaches the use of swelling and softening polymers. (Walker, col. 4, lines 46-50). Neither Walker nor Bobo teach or suggest that the membrane materials described by Bobo (for membrane 26,40) would behave as a hydrophilic material that would swell or soften. Therefore, Bobo's membrane materials are not compatible with the use of the hydrophilic material as required by Walker. Hence, the swelling and softening requirements of Walker catheter material teach away from using Bobo's membrane materials in Walker's catheter structure.

Accordingly, it is submitted that claim 1 is patentable over the cited references. Because claims 2-5, 7 and 9-27 are dependent claims of claim 1, they are believed to be allowable as well.

Claim 68 recites a stabilizing catheter comprising, among other features, a hydrophilic coating on an innermost surface of the tubing formed from one or more hydrophilic protein compatible materials.

Walker teaches a swellable cannula with a hydrophilic layer and a substantially non-hydrophilic layer, wherein the hydrophilic layer comprises at least two-thirds (2/3) of the cross-sectional area of the wall of the cannula. (Walker, abstract). In Walker, the hydrophilic layer can be the outer or inner layer, and swells and softens upon contact with an aqueous liquid by absorbing the liquid. (Walker, col. 3, lines 4-7, and col. 4, lines 6-9). The hydrophilic layer in Walker is not a coating, but comprises a separately formed structure that comprises the bulk of the cross-sectional area of the cannula. Walker teaches co-extruding both the hydrophilic layer and the non-hydrophilic layer simultaneously, further showing that the hydrophilic layer is a separately formed structure and not a coating. (Walker, col. 9, lines 18-20.) In contrast, claim 68 recites that the hydrophilic layer is a coating on the innermost surface of the tubing and, thus, must be formed after the formation of the tubing. (Specification, page 20, lines 1-13).

Moreover, Walker is only concerned with the physical properties of the hydrophilic materials, hence the only requirements for the hydrophilic materials are properties such as liquid absorption ratio and softening ratio. (Walker, col. 4, lines 23-45). By comparison, claim 68 of the present application restricts the material for the hydrophilic coating to protein compatible materials. The hydrophilic coating aims to resolve the problem of protein molecules sticking to the inner surfaces of the catheter, causing denaturing of the protein drug and "site loss". (Specification, page 2-3, lines 18-28 and 1-3). Protein molecules react differently to different hydrophilic materials, and not all hydrophilic materials are "protein-compatible" and suitable as a material for the hydrophilic coating. (Specification, page 21, lines 15-27). There is no teaching or motivation in Walker to use a protein-compatible hydrophilic material.

In addition, as discussed above with respect to claim 1, it would not have been obvious to combine Bobo's membrane material with Walker's cannula structure, because Walker's cannula

structure does not include a flexible membrane or a pressure monitoring structure that employs a membrane. There would have been no reason or motivation to employ Bobo's membrane material on Walker's cannula structure. Accordingly, the rejection of claim 68 is also respectfully traversed.

Dependent clam 87 further recites that the hydrophilic coating comprises materials applied to the innermost surface of the tubing through a surface treatment. While the Examiner stated that claim 87 is understood to be a product by process claim that is not limited to the manipulations of the recited steps, it is noted that claim 87 recites that the hydrophilic coating is applied to the innermost surface of the tubing. Such a "coating" on "the innermost surface of the tubing" has structural limitations that must be considered. Furthermore, Bobo's membrane material must be located on the exterior surface of the catheter body, to function in the manner described by Bobo. Accordingly, Bobo's membrane material could not be a coating on an innermost surface of a tubing. Furthermore, a co-extrusion process as described by Walker (Walker patent, Col. 9, ll. 18-20) would not provide a coating on an innermost surface of a tubing. Accordingly, the structural features of claim 87 are further distinguished from the Walker and Bobo references. Similar comments apply to dependent claims 88, 92, 93 and 94.

Claims 69, 89, 90, 91, 95, 96 and 97 are each dependent (directly or indirectly) on claim 1 or claim 68 and are believed to be allowable over the references of record at least for reasons discussed above with respect to claims 1 and 68.

None of the other references cited in the rejections (Ash et al, Brange et al, Nelson, Ekwuribe et al., or Van Antwerp et al.) address the above-noted distinctions over the Walker and Bobo references. None of those references would render it obvious to apply Bobo's membrane material on Walker's cannula structure. Indeed, each of those references was cited by the Examiner for other purposes. Accordingly, each of the above rejections is respectfully traversed.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date: December 26, 2006

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